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PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

David Ow

Serial No. **09/911,088**

Filed: **July 23, 2001**

For: **Methods for the Replacement,
Translocation and Stacking of
DNA in Eukaryotic Genomes**

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TECH CENTER 1600/2900

Art Unit: 1638

Examiner: **Helmer, Georgia L.**

RESPONSE TO ELECTION/RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Election/Restriction requirement mailed on January 29, 2003, a response which is due February 28, 2003, Applicant elects, with traverse, Group X directed to Claims 1-16, and 35-36, drawn to methods of obtaining site-specific gene replacement as they relate to ϕ C31 integrase, Cre reversible recombinases and/or plant cells.

Applicant makes the above election with traverse. Applicant submits that the presently claimed invention is a novel method for introducing polynucleotides into eukaryotic cells. The novelty of the invention lies at least in the use of an irreversible recombinase and two or more irreversible recombination sites in a receptor construct in addition to two or more complementary irreversible recombination sites in a donor construct. This novel method allows for the stable, site-specific replacement of a polynucleotide using a limited number of integration steps, which benefits are not provided in the prior art.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: U.S. Patent & Trademark Office, Commissioner for Patents, Washington, D.C. 20231, on February 28, 2003.

William L. Warren - Reg. 36,714

The Office Action states that restriction is required between the methods of obtaining site-specific gene replacement, and methods for obtaining site-specific gene replacement, comprising deleting undesired nucleotides because the inventions are unrelated. The inventions are stated to be unrelated since they are "not disclosed as capable of use together and they have different modes of operation, different functions or different effects." The Group Y inventions have different starting materials, use different steps, and produce different results than the Group X inventions. The Office Action further states that Claim 1 links Groups X and Y, and that the restriction requirement between the linked inventions is subject to the non-allowance of Claim 1. Upon allowance of Claim 1, the restriction requirement as to the linked inventions shall be withdrawn, and any claims depending from the allowable linking claim will be entitled to examination.

Applicant respectfully submits that the restriction requirement does not meet the requirements set out in Chapter 800 of the MPEP, and accordingly requests that the Examiner review and withdraw the requirement. Section 803.01 of the MPEP states that there are two requirements for restriction between patentably distinct inventions: 1) the inventions must be independent or distinct as claimed and 2) there must be a serious burden on the examiner if restriction is required. Applicant first submits that the Examiner has not demonstrated that it would be a serious burden to search and examine all of the claims together. The two groups of claims are within the same class and subclass, and therefore, easily searched together.

Applicant also respectfully submits that the inventions in Group X and Group Y are related, and accordingly requests that the Examiner review and withdraw the requirement. Examiner has cited Form Paragraph 8.20.02 as sent out at MPEP §808.01, asserting that the inventions in Group X and Group Y are unrelated. As described in MPEP §808.01, this form paragraph is only to be used "when claims are presented to unrelated inventions, e.g., a necktie and a locomotive bearing." The two sets of claims of the present invention are related, since they are both dependent on the same independent claim, and since both groups claim a method of using two or more irreversible recombination sites (IRS) in the same construct to achieve site-specific gene replacement. The common method relates the invention.

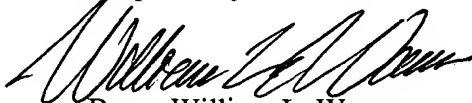
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In addition, the two inventions are not independent or distinct as claimed. The term "independent" means that there is no disclosed relationship between the two or more subjects, for
AO 866360.1

example, they are unconnected in design, operation, or effect (MPEP §803). Group X and Group Y are dependent since the two groups claim a method of using two or more irreversible recombination sites in the same construct to achieve site-specific gene replacement. The methods operate in the same manner to achieve the same effect, and furthermore, Group Y cannot be achieved without the use of the matter claimed in Group X. While Group Y claims a further step of using reversible recombination sites and a reversible recombinase to delete unwanted sequences in the replaced gene, it still achieves the same effect of replacing a gene using irreversible recombination sites. Additionally, the two groups are not distinct in nature since Group X would not be patentable over Group Y.

In summary, Applicant makes the above election with traverse. Applicant submits that the restriction is improper and respectfully requests that the Examiner review and withdraw the restriction requirement. The foregoing is submitted as a full and complete Response to the Office Action mailed January 29, 2003. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment to Deposit Account No. 19-5029. The Examiner is invited and encouraged to contact the undersigned attorney of record if such contact will facilitate an efficient examination and allowance of the application.

Respectfully submitted,


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